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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,925	06/20/2001	Seiichi Araki	MTSU-1001US	7925

21302 7590 10/22/2002

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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/22/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/806,925

Examiner

Ruth A. Davis

Applicant(s)

ARAKI ET AL.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 61-121 is/are pending in the application.
- 4a) Of the above claim(s) 61-120 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 121 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's amendment has been received and entered into the case. Claim 121 has been added. Claims 61 – 121 are pending.

As indicated in the previous Office communication mailed July 12, 2002, newly submitted claims 61 – 120 are directed to inventions that are independent and distinct from the invention of claims 1 – 60 and 121. The inventions of claims 61 – 120 are drawn to several unrelated methods of using a composition comprising a sugar cane extract. Specifically,

claims 61 – 75 are drawn to a method for preventing infection;

claims 76 – 90 are drawn to a method of using a vaccine adjuvant;

claims 91 – 105 are drawn to a method for preventing a disease; and

claims 106 – 120 are drawn to a method for promoting growth of humans or animals.

Applicant argues that the methods of claims 61 – 120 have unity of invention with originally presented claims 1 – 60 and 121 because the claimed product has the claimed activity and that a special technical feature exists between the invention of claims 1 – 61 and 121 and the methods of claims 61 – 120. Applicant indicates that the special technical feature is "the use of the composition to prevent or remedy infection."

However, as originally stated by applicant in the election response filed October 15, 2001 (paper number 9) the special technical feature was identified to be a sugar cane extract. This special technical feature was confirmed again in the amendment filed April 22, 2002. As evidenced by the references cited in the Office action mailed December 14, 2001, such a special

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technical feature does not exist, since the references disclose compositions comprising sugar cane extracts. As such, claims 61 – 120 are directed to inventions that are independent and distinct from the invention originally claimed (claims 1 – 60, 121).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 60 – 120 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 121, drawn to elected subject matter, has been examined on the merits. All arguments have been fully considered.

### *Drawings*

The drawings remain objected to because figures 3 and 4 are cut off and illegible.

According to MPEP 1893.03(f), drawings for the national stage application must comply with PCT Rule 11. While the copy of the drawings provided by the International Bureau has already been checked and should be in compliance with PCT Rule 11 and be acceptable, the examiner does indeed have the authority to require new or more acceptable drawings if the drawings were published without meeting all requirements under the PCT for drawings.

PCT Rule 11.6 states:

(c) On sheets containing drawings, the surface usable shall not exceed 26.2 cm x 17.0 cm. The sheets shall not contain frames around the usable or used surface. The minimum margins shall be as follows:

- top: 2.5 cm
- left side: 2.5 cm
- right side: 1.5 cm

- bottom: 1.0 cm

Since figures 3 and 4 are cut off, the drawings do not meet all requirements under PCT Rule 11.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 121 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 121 is drawn to a composition however is rendered vague and indefinite for reciting "a preventative" because the term is not adequately defined.

The claim is further indefinite for reciting "for infection" because it is unclear what kind of infection is prevented or remedied. For example, is the composition is a remedy for both bacterial infection and viral infection?

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claim 121 is rejected under 35 U.S.C. 102(a) as being anticipated by Kawai.

Applicant claims a composition for preventing or remedying infection in man and animals, the composition comprising a sugar cane derived extract as the active ingredient.

Kawai teaches a sugar cane extract (abstract).

Although the reference does not teach the composition can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.

5. Claim 121 is rejected under 35 U.S.C. 102(b) as being anticipated by Bueno.

Applicant claims a composition for preventing or remedying infection in man and animals, the composition comprising a sugar cane derived extract as the active ingredient.

Bueno teaches methods of obtaining pharmaceuticals from sugar cane as a raw material (abstract).

Although the reference does not teach the composition can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.

6. Claim 121 is rejected under 35 U.S.C. 102(b) as being anticipated by Tilby.

Applicant claims a composition for preventing or remedying infection in man and animals, the composition comprising a sugar cane derived extract as the active ingredient.

Tilby teaches compositions of sugarcane extracts (col.2 line 60-68).

Although the reference does not teach the composition can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to

create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.

7. Claim 121 is rejected under 35 U.S.C. 102(b) as being anticipated by Agar.

Applicant claims a composition for preventing or remedying infection in man and animals, the composition comprising a sugar cane derived extract as the active ingredient.

Agar teaches compositions of plant material (abstract, col.4 line 39-41) wherein the fibrous plant material is bagasse (or a sugar cane extract) (col.16 line 15-20).

Although the reference does not teach the composition can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.



8. Claim 121 is rejected under 35 U.S.C. 102(b) as being anticipated by Saska.

Applicant claims a composition for preventing or remedying infection in man and animals, the composition comprising a sugar cane derived extract as the active ingredient.

Saska teaches compositions of sugar cane molasses, a sugar cane extract (col.1 line 34-40).

Although the reference does not teach the composition can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.

Applicant argues that the specified use is not taught by the references and that Bueno does not teach pharmaceuticals, but pharmaceutical cellulose.

However, these arguments fail to persuade because as stated above, although the references do not teach that the composition can be used in the manner instantly claimed, the

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intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

In addition, the pharmaceutical cellulose of Beuno is a sugar cane derived extract (abstract).

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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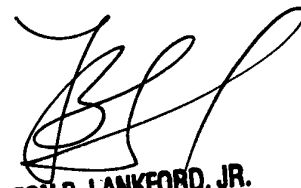
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
October 9, 2002

  
LEON B. LANKFORD, JR.  
PRIMARY EXAMINER